

REMARKS

Reconsideration and withdrawal of the rejections of the present application are respectfully requested in view of the amendments and remarks made herewith, which are believed to place the application into condition for allowance. Examiner Aulakh is thanked for courtesies extended during the interview on May 25, 2005 with Thomas Kowalski, Angela Collison, David Alcock, and John Normanton.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1, 8, 9, 12, 18-24, 30-33, 36, 37 and 42-54 are now pending. By this paper, claims 2-7, 10-11, 13-17, 25-29, 34, 35, and 38-41 are canceled, claims 42-54 have been added, and claims 1, 9, 12, 20, 23, 30 and 31 have been amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

It is submitted that these claims are patentably distinct from the prior art, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§§§101, 102, 103 or 112; but rather the remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

No new matter has been introduced by these amendments. Support for the amended recitations can be found throughout the specification.

II. THE OBJECTIONS TO THE SPECIFICATION ARE OVERCOME

The Office Action objected to the disclosure for allegedly failing to include a brief description of the drawings. The amendments to the specification made herewith are believed to comply with the Examiner's objection. Accordingly, reconsideration and withdrawal of the objections to the specification are respectfully requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112, ARE OVERCOME

Claims 26, 27, 30, and 38-41 were rejected under 35 U.S.C. §112, 1st paragraph, as allegedly failing to comply with the enablement requirement. The Office Action alleges that the specification is not enabling for any and all known disease conditions associated with steroid

sulphatase activity and would therefore require undue experimentation to demonstrate the effectiveness of the instant compounds in known animal models of all disease conditions associated with either an increased or decreased steroid sulphatase activity.

Applicants respectfully submit that the instant specification is enabling for disease conditions associated with steroid sulphatase activity, such as at pages 37 and 38, lines 20-35 and continuing on lines 1-12; and additionally on pages 69 through 75 of the specification as filed. Here, numerous examples of selected diseases associated with steroid sulphatase activity are provided, including cancer, diseases utilizing oestrogen therapy, neurodegenerative diseases, TH1-associated diseases, among many others. Further, Applicants also cite U.S. Patent Nos. 6,677,325; 6,159,960; and 6,017,904, all assigned to Sterix, the assignee of the present application, which collectively describe methods of inhibiting steroid sulphatase in subjects in need thereof. These methods of modulating steroid sulphatase activity have been found to be patentable and are submitted herewith as evidence that support exists for the various diseases disclosed in the instant specification.

The Office Action also contends that there are no working examples demonstrating the efficacy of the instantly claimed compounds in known animal models of all disease conditions associated with a modulation of STS activity. The instantly claimed compounds allegedly encompass several thousands of compounds that, in the absence of teaching, guidance, or working examples, would require undue experimentation to demonstrate the effectiveness of the compounds in known animal models of all diseases associated with STS activity.

Applicants respectfully submit that the specification does provide guidance as to the use of the instant compounds in disease conditions associated with a modulation of STS activity. In particular, the specification clearly enables the skilled artisan to make and use the instantly claimed compounds in assays and animal models described on pages 47 through 51, page 67 at lines 23-35, and on page 69. The results of two assays are described and presented in Figures 2 and 3. Therefore, based on the disclosure of the instant application, one of skill in the art would not require undue experimentation to make and use the invention (MPEP §2164.06). Although the instant application relates to several compounds that modulate STS activity, “[a]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance” (*In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977)).

Consequently, reconsideration and withdrawal of the rejections under §112, 1st paragraph are respectfully requested.

In addition, claims 1-41 were rejected under 35 U.S.C. §112, 2nd paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. In particular, the Office Action alleges that:

- In claims 1-4, the position of attachment of variable R1 is not defined.
- In claims 1, 3, 5, and 7, the size of the nitrogen-containing ring is undefined;
- Claims 1-8 recite a variable G substituent that is not defined in the specification;
- Claims 3-8 and 23 recite the limitation of an “unsaturated 6-membered carbocyclic ring”, which allegedly lacks antecedent basis;
- In claims 10-17, the term “G or the hydrocarbyl group” is vague and confusing, because the variable G substituent is already defined as a hydrocarbyl group according to claim 9;
- Claim 12 is indefinite for the phrase “such as”, because it is unclear whether the limitations following the phrase are part of the claimed invention;
- Claims 12-15 and 17 recite a broad recitation of a C₁-C₁₀ alkyl group, C₁-C₁₀ haloalkyl group, (CH₂)₁₋₁₀ aryl, phenyl, phenyl-C₁₋₁₀ alkyl, cycloalkyl and C₁-C₁₀ alkene group and the claims also recite a C₁-C₆ alkyl group, C₁-C₆ haloalkyl group, (CH₂)₁₋₅ phenyl, etc., which represents a narrower recitation of the broad range;
- Claims 20 and 23, the term “wherein the or each alkyl or cycloalkyl or alkenyl or optionally contain one or more heteroatoms or groups” is vague and indefinite since its meaning is unclear;
- Claim 29 is a substantial duplicate of claim 28;
- Claim 30 contains a term “modulating STS activity”, which is indefinite because it is unclear whether the activity is inhibited or stimulated; and
- Claims 25-29, 34, 35, and 38-41 provide for the use of a compound, but does not set forth any steps involved in the method of process and therefore, it is allegedly unclear what method or process is encompassed by these claims.

The amendments to the claims, made herewith, are now believed to fully comply with the provisions of §112. Reconsideration and withdrawal of the rejections under §112, 2nd paragraph are therefore respectfully requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §101 ARE OVERCOME

Claims 25-29, 34, 35, and 38-41 were rejected under 35 U.S.C. §101 because the alleged claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim that is not a proper process claim under 35 U.S.C. §101.

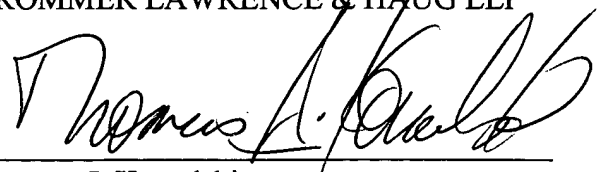
This paper has canceled claims 25-29, 34, 35, and 38-41. New claims 43-54 now recite methods setting forth distinct steps. Consequently, reconsideration and withdrawal of the rejections under §101 are warranted and respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, it is believed that the claims in this application are in condition for allowance, and early and favorable consideration thereof is earnestly solicited.

Respectfully submitted,
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